MDCH Comments and Recommendations for CON Standards Scheduled for 2008 Review Presented to CON Commission January 24, 2008

OPEN HEART SURGERY (OHS) SERVICES			
(Please refer to 1.14.08 MDCH staff analysis for additional detail – attached)			
All Identified Issues	Issues Recommended	Recommended	Other/Comments
	as Requiring Review	Course of Action to	
		Review Issues	
1. Continued	Yes	Department	CON regulation of
regulation of OHS		recommends that the	OHS services appears
services under CON		OHS standards be	to be working in
		reviewed again in	Michigan and has
		2011, following	broad support.
		implementation of the	
		recently approved	
		OHS standards.	
2. No additional	No	None at this time	Thoroughly discussed
modifications to the			by the OHS SAC in
Commission approved			2007, with the
OHS standards			Commission taking
			Final Action at its
			December 11, 2007
			meeting to move the
			SAC recommended
			language, with the
			Department's
			Proposed
			Amendments to the
			Methodology (S-3),
			forward for review by
			the JLC and the
			Governor.

Recommendation: The Department recommends that the Commission review the OHS standards during the next review cycle scheduled in 2011. The currently approved standards have yet to be implemented, and then have the opportunity to be evaluated before any changes are made to the standards.

Michigan Department of Community Health MEMORANDUM Lansing, MI

DATE: January 14, 2008

TO: Irma Lopez

FROM: Umbrin Ateequi

RE: Summary of Public Hearing Comments on Open Heart Surgery (OHS)

Standards and MDCH Policy Staff Analysis

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Open Heart Surgery (OHS) standards on October 31, 2007, with written testimony being received for an additional 7 days after the hearing. The information below is a summary of the testimonies received. The complete oral and written testimonies are included in the January 24, 2008 CON Commission meeting binders. The facilities/organizations represented were as follows:

Oral Testimony Summary

None

Written Testimony Summary

Five individuals provided written testimony, representing five facilities/organizations.

1. Robert Meeker, Spectrum Health:

Endorse the work of the recently completed Open Heart Surgery Standards Advisory Committee and recommend final adoption of the proposed CON Review Standards for OHS services, with the inclusion of the S-3 need methodology. Do not believe that any additional modifications are required to these standards at his time, and recommend that they not be reopened for substantial revision for three (3) years.

2. Patrick O'Donovan, William Beaumont Hospital:

Support the continued regulation of Open Heart Surgery services. Would further like to commend the SAC for its recent work in revising the standards, specifically, its recommendation to maintain the current standard minimum of 300 adult open heart procedures. Further support the efforts of the MDCH staff and the Commission in revising the methodology used to project need. As a result of these recent proposed revisions, Beaumont does not feel it is necessary for the Commission to review the standards in 2008. Beaumont also urges the

Commission to continue pressing the Department to routinely and consistently enforce CON regulation, including volume requirements.

3. Sean Gehle, The Michigan Health Ministries of Ascension Health:

Look forward to participating in a deliberative and open discussion on any potential changes proposed to these standards consistent with the statutory language requiring the Commission to review and, if necessary, revise each set of CON review standards at least every three (3) years. Wholeheartedly support the review of CON standards on the required three year schedule; not as some have suggested, three years from the last time the standard was modified.

4. *Melissa Cup, Wiener Associates*:

Comments pertain specifically to the CON Standards for Open Heart Surgery Services with Proposed Amendments (S-3). Suggest some modifications to the proposed language that the Department has added to allow them to update the utilization weights on an annual basis, without having to go through the CON Commission for permission to do so.

(Department Note: The suggested modifications have been adopted in the Final OHS language approved by the Commission at its December 11, 2007 meeting.)

5. *Marsha Manning, EAM/General Motors*:

Preface EAM remarks by reporting that General Motors, and colleagues at Chrysler and Ford, have found that strong CON programs in the U.S. have been effective in controlling costs and improving the quality of healthcare services for employees and retirees if they are strong and well-developed, both in concept and implementation. Have found that the Michigan CON standards are among the most effective CON programs in accomplishing this objective in the approximately ten states in which these companies have significant membership.

Agree that the Commission should comply with the CON statutory requirement that each CON standard be reviewed every three (3) years for possible revision. This should mean that standards are not considered for possible review until three (3) years after the last time they were reviewed, unless there is some compelling reason, such as new developments in medical practice or other factors affecting the service. Some of the standards posted for this hearing include several of the standards that have undergone reviews in 2006 (Hospital Beds) and in 2007 (Cardiac Catheterization and Open Heart Surgery). Accordingly, would recommend that the next possible review of the Hospital Beds standards, last modified in 2006, be rescheduled for possible review in 2009. The next review of the two cardiac standards should be rescheduled for possible review in 2010.

The following process changes should be approved by the Commission for all CON standards:

1. All CON standards that rely upon data should automatically use the most currently available data from either the MIDB or the MDCH Annual Surveys. The update of data should not require a request of

- the Commission or the approval of a SAC. Annually updating the data and its impact upon the standards should be done no later than 60 to 90 days following receipt of the data.
- 2. Every CON standard that requires a projection of minimum volumes to justify a new program should be based on actual, historical data and not based upon the unverifiable projections of future referrals.
- 3. Organization/providers seeking to start a new CON approved program should not use any data to support their application that would result in a current CON approved program falling below the CON minimum volume for that service.

In addition to these comments regarding the 2008 work plan, would like to support the proposed changes in the CON standards for Cardiac Catheterization and Open Heart Surgery, including the modification to the formula for predicting the need for any additional open heart surgery programs.

Policy Issues to be addressed

Continued regulation of OHS services under CON

Based upon the testimonies provided, as well as the goals being promoted by MDCH, the Department supports continued regulation of Open Heart Surgery (OHS) Services under CON.

CON Commission approved OHS standards

The OHS standards underwent a thorough review by a Standard Advisory Committee (SAC) in 2007. The SAC completed its work on July 11, 2007 and provided the Commission with draft language at the September 18, 2007 meeting, thoroughly addressing all of its assigned charges, except one. The 2007 OHS SAC had as one of its goals, to review the methodology (adopted over 20 years ago) and make the appropriate updates. As final analytic data were not available to the SAC upon its statutorily designated 6 month deadline, the SAC recommended that the Department generate the needed data to permit updating of the relevant utilization weights.

Refinements to the OHS methodology for projecting the need for additional OHS programs in Michigan (proposed by MDCH and identified as S-3) were developed pursuant to strong requests by the SAC, the public, and the Commission. In developing this model, the Department worked with a broad group of stakeholders and solicited extensive public comment/input. These refinements have made much progress in strengthening the open heart methodology and have gone a long way to improve the predictability of this process.

Following much work and analyses, the Department posted draft language for consideration at the October 31, 2007 Public Hearing. This language included Proposed Amendments that incorporate the revised methodology of S-3. As can be seen from the various testimonies received (as the OHS standards are scheduled for review again in

2008, according to the scheduled three (3) year review cycle), the Department has received overall strong support for these recommended refinements to the OHS methodology. In addition, as these revisions are complete and address all issues raised to date, the Department is in agreement with the public testimony that the CON standards for OHS do not need to be reopened for revision in 2008. The CON Commission just recently, at its December 11, 2007 meeting, accepted the OHS SAC recommendations with the proposed amendments which includes the S-3 language, and moved it forward to the Joint Legislative Committee and the Governor for the 45-day review period. The approved standards have yet to be implemented, and then evaluated before any new changes are made to the standards. The Department recommends that the Commission review the OHS standards in 2011.